

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed May 18, 2009. Currently, claims 1-30 remain pending of which claims 1-8 and 21-30 were previously withdrawn. Claims 9-20 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 9 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), hereinafter Hanson. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). Nowhere does Shortt appear to disclose providing a “an inner tubular shaft disposed within an outer tubular shaft ... and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof”.

Instead, Shortt appears to disclose, in the cited Fig. 2 as well as Figs. 7A-7C, an inner shaft disposed within a balloon which extends proximally to a position near the distal end of the inner tube. Accordingly, Shortt does not appear to disclose an element corresponding to an outer tube having a distal end or an inflatable balloon having a proximal end attached to the distal end of an outer tube. (If the disclosure of Fig. 2 is to be taken literally, Shortt does not appear to disclose an inflatable balloon having “a distal end attached to the inner shaft near the distal end thereof”, the inflatable balloon and the inner shaft apparently being distally co-terminal. *near*: At a little distance, in place, time, manner, or degree.) Furthermore, nowhere does Shortt appear to disclose, “inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent”.

Additionally, nowhere does Morales appear to remedy the shortcomings of Shortt. Morales does not appear to disclose a catheter having an inner tube and an outer tube, but describes the delivery catheter (11) merely as: "Delivery catheter 11 has an expandable portion or balloon 14 for expanding stent 10 within coronary artery 15 or other vessel such as saphenous veins, carotid arteries, arteries, and veins." Accordingly, neither Shortt nor Morales appear to disclose a system having both an inner tube and an outer tube and "an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof".

Further, as acknowledged in the Office Action, "Shortt fails to disclose crimping the stent onto the balloon as the step of crimping is done prior to the stent being placed over the balloon according to the disclosure of Shortt." Shortt characterizes the process of using his mould as "Pressure is applied to the delivery system through a luer and the mould is heated. This combination of heat and pressure secures the stent to the balloon." By contrast, Morales characterizes his method as: "The present invention is directed to a crimping tool that can repeatedly provide a uniform and tight crimp to ensure the low profile diameter of the stent on the balloon portion of the catheter, and to ensure that the stent remains firmly attached until it is implanted in the vessel by expanding the balloon." Accordingly, modifying the method of mounting disclosed by Shortt, which asserts that it relies upon pressure and heat to secure the stent to the balloon by substituting the method of Morales which asserts that it relies upon mechanical crimping would appear to impermissibly alter the principle of operation of Shortt. (MPEP 2143.01, VI.)

The addition of Hanson, as illustrated in Figs.15 and 16, does not appear to overcome the deficiencies of Shortt in view of Morales in that the disclosure of Hanson does not appear to disclose a catheter having an inner tube and an outer tube, but rather discloses: "Distal portion 16 is fixed to catheter 12 by standard means known in the art. For instance, distal portion 16 may be bonded at its ends by adhesive to the catheter in an integral manner, or may be made one-piece with the catheter as is known in the art. Distal end portion 16 comprises balloon 22, which is constructed and arranged for expansion from a contracted state to an expanded state.", at col. 10, lines 4-11. The inclusion of a proximal dam or stop internal to the balloon of Shortt as taught by Hanson would appear to require a further impermissible departure from the operating principle of Shortt (MPEP

2143.01, VI.) and would appear to ignore the explicit teaching of Shortt that: “In order to ensure proper placement of the stent at the treatment site, one must avoid relative movement between the stent and the balloon. One means by which this risk of relative movement between the balloon and stent may be lessened is to form pillows on the balloon on either side of the stent to help prevent the stent from slipping off the balloon. Another means of achieving this object is to securely mount the stent onto the balloon.” (Col. 2, lines 4-11) Accordingly, one of ordinary skill in the art, familiar with the teaching of Shortt, would not be motivated to modify Shortt by omitting the distal pillow as suggested in the Office Action as this would, according to the teaching of Shortt, appear to render the balloon catheter of Shortt unsuited for its intended purpose of retaining the stent. The proposed modification of the operating principle of Shortt would appear to disable one mechanism for stent retention without enabling the alternative provided. (MPEP 2143.01, V.)

For at least the reasons discussed above, Shortt in view of Morales and Hanson would appear to fail the Graham inquiry with respect to both the elements of the invention and the motivation of one of ordinary skill in the art.

“the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391 (2007).” (MPEP 2141, II.)

Therefore Applicants respectfully request that the rejection of independent claim 9 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly claims 10-20, which depend from nonobvious independent claim 9, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

While appreciating that the above rejection is based upon unidentified prior art, Applicants note that, as disclosed by Shortt, the prior art does not appear to be operable. While one of ordinary skill in the art might understand that “TFE” may informally be used to denote polytetrafluoroethylene, Shortt explicitly states that “TFE” is being used to denote “tetrafluoroethylene” at col. 2, line 13. Tetrafluoroethylene has a boiling point of -76.3 °C which would appear to make it unsuited as a sheath in a process which is said to require exposure of a balloon contained within the sheath to temperatures of 93-180 °C. While the reference need not be enabling, it may only be relied upon for what it teaches, in this case, the sole material disclosed as suitable for the containment sheath of Shortt appears to disclose no more than the use of a gaseous containment sheath.

Claims 9 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975) and Hanson et al. (U.S. Patent No. 5,893,868), hereinafter Hanson. After careful review, Applicant must respectfully traverse this rejection.

Turning to the second rejection which the Office Action characterizes as based upon the improved method of Shortt rather than the prior art disclosure of Shortt, each of the deficiencies of the references as noted above appear to apply singly and in combination to the second rejection over Shortt in view of Morales and Hansen. As previously noted, the balloon catheter of Shortt, whether illustrated in Fig. 2 or Figs. 7A-7C, does not appear to disclose “an inner tubular shaft disposed within an outer tubular shaft ... and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof”. Contrary to the Office Action’ comment, the cited Figs. 7A-7C do not appear to disclose the steps of the method, but rather illustrate “a sectional view showing a standard profile, a tapered profile, and a reduced profile at proximal and distal ends”. The moulding process of Morales, as depicted in Fig. 3, appears to place a stent/balloon assembly into a mould cavity that is either about 3/4 the diameter of the stent/balloon or about 3/8 the diameter of the stent/balloon depending upon how the dimension of the channel in the mould is interpreted within the figure. In either event, once the stent/balloon is placed within the mould, it would not appear to be possible to achieve the

condition recited in claim 9: “the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto” or to achieve “inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent” since those elements would appear to be in contact prior to inflation. As noted at col. 4, lines 63-67, the split mould of Shortt does not require sufficient clearance to allow the sheath to be loaded over the stent. Further, as noted above, the addition of Morales to Shortt does not appear to overcome the deficiencies of Shortt and additionally appears to impermissibly alter the operating principle of Shortt. As also discussed above, Hanson does not appear to overcome the deficiencies of Shortt in view of Morales and it would appear that an attempt to modify the method of Shortt by the inclusion of a stop internal to the balloon and further by the omission of the distal pillow would impermissibly alter the operating principle of Shortt in a manner contrary to the disclosure of Shortt.

For at least these reasons, it would appear that Shortt in view of Morales and Hanson as applied to the method disclosure of Shortt also fails the Graham inquiry and Applicants respectfully request that the rejection of independent claim 9 be withdrawn.

The addition of the protective sleeve of Miraki et al. (U.S. Patent No. 5, 704,845); the flared tube of Johnson (WO 02/066095); the plurality of crimping elements of Motsenbocker et al. (U.S. Patent No. 6,629,350), and/or the temperature range of Jendersee et al. (U.S. Patent No. 5,836,965), which elements do not appear in nonobvious independent claim 9 would not appear to affect the patentability of pending claim 9 in which those elements do not appear.

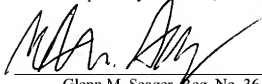
Accordingly claims 10-20, which depend from nonobvious independent claim 9, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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